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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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09/046,840

03/24/98

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EN2-56 (I-IV3)

HM11/0612  
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EXAMINER

GUZO, I

ART UNIT

PAPER NUMBER

1636

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DATE MAILED:

06/12/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

**OFFICE ACTION SUMMARY**

☒ Responsive to communication(s) filed on 3/24/98

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three (3) month(s), ~~or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) 68-84 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 68-84 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

**Application Papers**

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Since this application is a divisional of pending parent application 08/822,963, applicants need not submit a new computer readable form of the Sequence Listing. However, the specification must contain a paper copy of the Sequence Listing and applicants must request in writing that the CRF in the parent case be used to prepare a file for the offspring. In addition, applicants must submit a statement that the paper copy of the Sequence Listing in the offspring is identical to the computer readable form submitted in the parent case.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

2. Claims 68-79 and 81-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong-Staal et al.

Applicants claim a viral vector (i.e. a vector derived from a retrovirus or adeno-associated virus (AAV)) wherein said vector can produce a second vector or nucleic acid when introduced

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into a packaging cell and wherein the vector is capable of expressing a heterologous sequence in a target cell of interest.

Wong-Staal et al. (U.S. Patent #5,650,309, issued 7/22/97, priority back to 5/16/95, see whole document, particularly Figs. 11-13, Claims 1-15 and Columns 6-7 and 16-18) recites the generation of viral vectors comprising sequences from retrovirus and AAV genomes wherein said vectors can produce a second vector (i.e. single or double stranded RNA or DNA), wherein said vectors comprise a promoter(s), integration sequence, terminator sequence, etc. and packaging cells for these vectors wherein the packaging cell comprises sequences for the envelope portion of the vector (optionally stably integrated into the chromosomal DNA of the cell) and two packaging components for the surface or envelope of the vector (i.e. packaging components for the AAV or retroviral vectors can be provided in the packaging cell). Wong-Staal et al. therefore teaches the claimed invention.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 68 and 70-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Salmons et al.

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Applicants claim a first vector which can be a viral nucleic acid wherein said first vector is capable of producing a second vector (of a different chemical nature) in a packaging cell wherein the second vector is capable of expressing an exogenous gene in a target cell and said vector contains a promoter(s), terminator sequences, enhancers, etc.

Salmons et al. (Human Gene Therapy, Vol. 4, 1993, pp. 129-141, see whole article, particularly Fig. 3 and pages 133-135) recites a first retroviral vector wherein said vector is capable of producing a second vector (of a different chemical nature) in a packaging cell line wherein the second vector is capable of expressing an exogenous gene in a target cell and said vector contains a promoter, enhancer, terminator sequences, etc. Therefore, Salmons et al. teaches the claimed invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 68-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 (and dependent claims) are vague in the recitation of the phrase "...is capable of producing..." or "...is capable of providing..." or "...is capable of expressing..." since the capacity

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of a compound or composition to perform some function is merely a statement of a latent characteristic of said compound or composition and said language carries no patentable weight.

Claim 78 is vague in that it is unclear what applicants mean by a cell line which is "native" to a viral vector, since a viral vector can contain portions of different viruses, each with their own "native" cell lines. It is also unclear what applicants mean by the term "native", i.e. a cell which can support replication of the virus or a cell which can be infected by the virus but not produce progeny virions, etc.?

Claims 81-84 are vague in that applicants recite sequences of a surface or envelope component are integrated into the chromosomes of the packaging cell line. Since the sequences of a surface or envelope component are usually proteins, it is unclear how protein sequences can be integrated into the chromosomes of the packaging cell line.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242 or (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo  
June 10, 1998

DAVID GUZO  
PRIMARY EXAMINER

A handwritten signature in cursive script, appearing to read "David Guzo", written in black ink.